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UNITED STAT DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/161,122	09/25/98	JIN	H 7682-45

EXAMINER	
BRUMBACK, B	
ART UNIT	**PAPER NUMBER**
1642	12

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DATE MAILED: 02/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/161,122	Jin et al.
Examiner	**Group Art Unit**
Brenda Brumback	1642

☒ Responsive to communication(s) filed on *Dec 15, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) *1, 3-12, 14-17, and 19-24* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2, 13, and 18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 12/15/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/161,122 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 1-24 are pending. Claims 1, 3-12, 14-17, and 19-24 have been withdrawn from consideration as drawn to a nonelected invention. Claims 2, 13, and 18 are under examination.

Sequence Disclosures

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is given the same time period as that for the present action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR

1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Drawings

4. The drawings are objected to because they do not contain references to the sequence disclosures by sequence identifier (SEQ ID NO:). When a sequence is presented in a drawing, the sequence must be included in the Sequence Listing and the sequence identifier must be used, either in the drawing or in the Brief Description of the Drawing (see MPEP 2422.02). Correction is required.

Specification

5. The disclosure is objected to because of the following informalities.

All nucleotide and amino acid sequences embedded within the text of the disclosure must be referenced by sequence identifiers (SEQ ID NO:) (see MPEP 2422.03). Correction is required.

The specification does not contain continuing data for the provisional applications. Correction is required.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Oath/Declaration

6. The domestic priority data in the Declaration is defective. Provisional applicant 60/069,153 does not have the same inventorship as the present application and is drawn to an unrelated invention. A new Declaration correcting the provisional data is required. Because priority cannot be established to provisional application 60/069,153 filed 09/26/97, for purposes of examination, the priority date of the present application has been established based on provisional application 60/084,133, filed 05/04/98.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 2 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 (and to claims 1-13 and 14 to the extent that they read on claim 15) of copending Application No. 09/368,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim

15 of the copending application is drawn to an infectious RSV particle comprising a heterologous sequence derived from the genome of another strain of RSV and claim 2 of the present application is drawn to an infectious RSV particle comprising heterologous sequences derived from the two strains of RSV. Thus, the subject matter of the referenced claims is essentially the same or obvious over those of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

8. Claims 2, 13 and 18 are objected to because of the following informalities:

At the first recitation of RSV, the entire virus name should be spelled out for clarity, *i.e.*, respiratory syncytial virus (RSV).

In claim 2, first occurrence in line 3, "RSV" is incorrectly written. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 2, 13, and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (WO 97/12032, of record as reference AB in Paper # 6; hereinafter Collins '032). As was discussed previously, the priority date of the present application has been determined to be that of the earliest confirmed provisional application referenced in applicant's Declaration: SN 60/084,133, filed 05/04/98.

The claimed invention is drawn to an isolated infectious RSV particle comprising a chimeric RSV genome or antigenome encoding antigenic polypeptides of RSV subgroups A and B and to a vaccine comprising a chimeric RSV, the genome of which contains the reverse complement of an mRNA coding sequence encoding G and F genes of both RSV subgroups A and B operatively linked to a polymerase binding site, and a pharmaceutically acceptable carrier.

Collins '032 teaches isolated infectious RSV particles comprising chimeric genomes or antigenomes of cDNA which are the reverse complement of the RSV RNA (see the abstract; page 3, lines 1-17; and page 4, lines 16-26) operatively linked to a transcriptional T7 promoter, and a transcriptional terminator (see page 5, lines 33-35 and page 6, lines 15-23). Collins '032 teaches that the RSV genome or antigenome can be modified to include nucleotide sequences encoding F and G proteins of different RSV subgroups (see page 5, lines 16-20, and page 21, lines 19-32). Collins '032 teaches that the RSV subgroups are designated as A and B (see page 6, line 34, through page 7, line 7). Collins '032 teaches that inclusion of the G protein gene of RSV subgroup B broadens the response to vaccines comprising the chimeric virus particles to cover a wider spectrum of the relatively diverse subgroup A and B strains present in the human

population (see page 19, lines 1-15). Finally, Collins '032 teaches vaccine compositions comprising the chimeric RSV viruses and a pharmaceutical carrier (see page 20, lines 6-25).

b. Claims 2 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (Proc. Natl. Acad. Sci., 92:11563-11567, 1995; of record as reference AK in Paper # 6, hereinafter Collins 1995).

The claimed invention is drawn to an isolated infectious RSV particle comprising a chimeric RSV genome or antigenome encoding antigenic polypeptides of RSV subgroups A and B and to a vaccine comprising a chimeric RSV, the genome of which contains the reverse complement of an mRNA coding sequence operatively linked to a polymerase binding site, and a pharmaceutically acceptable carrier.

Collins 1995 teaches an isolated infectious RSV particle comprising cDNA encoding a complete positive -sense antigenome operatively linked to the promoter for T7 RNA polymerase, a hammerhead ribozyme, and tandem terminators of T7 transcription (see the abstract and page 11564, second full paragraph bridging columns 1 and 2). Collins 1995 teaches that the infectious RSV particles can be engineered to enhance their immunogenicity and to induce a level of protection greater than that provided by natural infection. Finally, Collins teaches a chimeric virus incorporating genes of RSV subgroup B into the subgroup A particles, in order to broaden the response to the vaccine to cover a wider spectrum of the relatively diverse subgroup A and B strains present in the human population (see page 11567, last paragraph).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Collins 1995.

The claimed invention is drawn to an isolated infectious RSV particle comprising a chimeric RSV genome or antigenome encoding antigenic polypeptides of RSV subgroups A and B and to a vaccine comprising a chimeric RSV, the genome of which contains the reverse complement of an mRNA coding sequence encoding G and F genes of both RSV subgroups A and B operatively linked to a polymerase binding site, and a pharmaceutically acceptable carrier.

As previously described, Collins 1995 teaches an isolated infectious RSV particle comprising cDNA encoding a complete positive-sense antigenome. Collins 1995 teaches that the RSV particles express an abundant amount of the F protein (see page 11565, column 1, first partial paragraph, last sentence). Lastly, Collins teaches incorporating the G protein gene of RSV subgroup B into the subgroup A particles, in order to broaden the response to the vaccine to cover a wider spectrum of the relatively diverse subgroup A and B strains present in the human population (see page 11567, last paragraph). Collins 1995 differs from the claimed invention in that he does not specifically teach the infectious particles as comprising coding sequences for the

F and G genes from both subgroups A and B. Based on the teachings found in Collins 1995, one of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have assembled the chimeric RSV particles to incorporate both the F and G genes from the two subgroups of RSV, in order to maximize the vaccine efficacy for both subgroups.

Conclusion

11. No claims are allowed.

12. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
February 5, 2001

Brenda Brumback
Brenda Brumback,
Patent Examiner

Application No.: 09/161,122

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:

Applicant Must Provide:

- [X] An initial computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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